

BEFORE THE BOARD OF ALTERNATIVE HEALTH CARE
DEPARTMENT OF LABOR AND INDUSTRY
STATE OF MONTANA

In the matter of the amendment) NOTICE OF AMENDMENT
of ARM 24.111.301 definitions,)
ARM 24.111.511 naturopathic)
physician natural substance)
formulary list, ARM 24.111.602)
direct-entry midwife)
apprenticeship requirements, and))
ARM 24.111.613 required reports)

TO: All Concerned Persons

1. On November 18, 2004, the Board of Alternative Health Care published MAR Notice No. 24-111-18 regarding the public hearing on the proposed amendment of the above-stated rules at page 2786 of the 2004 Montana Administrative Register, issue no. 22.

2. A public hearing on the proposed amendment of the above-stated rules was held on December 9, 2004.

3. The Board of Alternative Health Care (Board) has thoroughly considered all of the comments made. A summary of the comments received and the Board's responses are as follows:

GENERAL COMMENTS:

Comment 1: One commenter objected globally to all proposed amendments in MAR Notice No. 24-111-18 as going beyond the original intended scope of the initial authorizing legislation and on the grounds that licensees are not educationally prepared for the privileges sought.

Response 1: The commenter did not specify in what respect ARM 24.111.301, ARM 24.111.602, or ARM 24.111.613 are in excess of the Board's statutory authority over direct-entry midwives. The proposed amendments relating to those three rules do not grant any privilege to direct-entry midwives that doesn't already exist under the current administrative rules. ARM 24.111.301 is a definitions rule and ARM 24.111.613 provides clarification on reports that are already required for direct-entry midwives. The proposed amendment to ARM 24.111.301 continues to require personal supervision of all direct-entry midwife apprentices but would allow, with Board approval, indirect supervision during the final level of apprenticeship. The Board determined that the educational and experience requirements set forth in statute and rules sufficiently prepare direct-entry midwife apprentices to practice safely under indirect supervision during the final level of their apprenticeship. The Board is authorized to set standards governing licensure, education requirements, and

criteria limiting apprenticeships under 37-1-131 and 37-27-105, MCA. Comments on ARM 24.111.511 are addressed below.

24.111.511 NATUROPATHIC PHYSICIAN NATURAL SUBSTANCE FORMULARY LIST

Comment 2: Several commenters opposed the current formulary either in total or as to specific substances listed in the formulary that were not included in the proposed notice and are not being amended at this time.

Response 2: The Board declines to address comments relating to sections of the current formulary rule that the Board did not include in the proposed notice and that are not being amended. Comments received regarding substances in the current formulary that remain unchanged are not timely or relevant to this rule notice. For edification of the commenters, however, the Board notes that a letter co-written by the attorneys for the Montana Board of Pharmacy and the Montana Board of Medical Examiners dated August 28, 2002, expressed that the then-existing formulary was within the scope of the Board's authority to adopt. To date, no amendments have been made to the formulary rule since the date of the above referenced letter. A copy of the referenced letter may be obtained from the Board office.

Comment 3: Several commenters questioned the Board's authority to amend the rule by adding to the formulary, in total or as to specific substances or classes of substances, as being in excess of the Board's legislative authority and on the grounds the drugs are synthetic, semi-synthetic, or are legend drugs as defined in 50-31-301, MCA.

Response 3: The Board has concluded that the proposed additions to the formulary (except as otherwise provided in response #4) are within the statutory authority granted the Board under 37-26-301(1), (2) and (3), MCA. The Board's conclusion is based upon the Board's collective knowledge of naturopathic pharmacology, consultation of recognized naturopathic medicine resources, reviewing the curricula of several approved colleges of naturopathic medicine and information on available naturopathic pharmacology continuing education courses. The Board determined it prudent to clarify that ketoconazole is for topical use, and has amended subsection (3)(v) accordingly.

Comment 4: Several commenters stated that the quinolones are synthetic and should not be included in the formulary.

Response 4: The Board has determined that the issue of whether the quinolones are synthetic remains unsettled among recognized authorities. The Board has therefore chosen not to include floroquinolone and its derivatives (ciprofloxacin, levofloxacin and ofloxacin) in the formulary at this time pending further study and has amended the rule accordingly.

Comment 5: Some commenters questioned whether doctors of naturopathic medicine (ND) are sufficiently trained and educated in pharmacology and whether NDs understand the potential for side effects, drug interactions, abuse of drugs and serious complications of drugs including death.

Response 5: Pharmacology is included in the curricula of approved naturopathic medical colleges, per 37-26-103(1), MCA. The national certification examination, as required for ND licensure in Montana, tests applicants' knowledge of pharmacology. Moreover, in contrast to the continuing education requirements for other health care providers, NDs are required to obtain at least five continuing education credits annually in naturopathic pharmacy, which amounts to a third of the total annual continuing education obligation of NDs. The Board fully recognizes the need for NDs to be well educated in pharmacology and has determined that this is achieved through education, licensure examination and required continued education. Montana licensed NDs understand the potential for side effects, drug interactions, drug abuse and serious complications of drugs.

Comment 6: One commenter expressed general concern about suboptimal use of antimicrobials leading to more resistant strains of organisms.

Response 6: The Board is aware of public health issues relating to the suboptimal use of antimicrobials. As previously stated, pharmacology is included in the curricula of approved naturopathic medical colleges and antimicrobials are covered in this pharmacology coursework. The Board notes that the Montana Board of Pharmacy initiated an informal survey in Missoula, MT, a number of years ago, regarding the prescribing of antibiotics by NDs. The survey results showed unequivocally that there existed no suboptimal prescribing of antibiotics by NDs during the period encompassed by the survey.

Comment 7: Several commenters opposed inclusion of oxycodone and hydrocodone in the formulary on the basis of their great potential for diversion and abuse.

Response 7: Hydrocodone has been included in the formulary list since the formulary's initial adoption in 1998. (See the Board's response #2.) The Board's screening panel has received no complaints since 1998 regarding the diversion or abuse of hydrocodone by NDs, or complaints alleging that NDs are facilitating their patients' abuse of hydrocodone. Further, the Board's screening panel has received no complaints about prescribing practices of NDs or any formulary-related complaints at all. The Board recognizes that oxycodone has great diversion and abuse potential, but there exists no evidence (and the commenters presented none) that NDs are more apt than other authorized prescribers to divert or abuse oxycodone, or facilitate or contribute to their patients' abuse of the drug. As previously stated, the NDs' education includes pharmacology

and the national certifying examination required for licensure in Montana tests the applicants' knowledge of pharmacology.

Comment 8: One commenter pointed out that "prgenenolone" in subsection (10)(a)(vi) contains a typographical error and that the name of the substance should be spelled as "pregnenolone".

Response 8: The Board acknowledges the misspelled word and has amended the rule accordingly.

Comment 9: One commenter requested that the Board add metformin and alendronate to the formulary.

Response 9: The Board is unable to add substances to the formulary at this time that were not included in the proposed rule notice, as the public would not be provided notice of such changes or any opportunity to comment on the amendments.

Comment 10: One commenter requested that ephedra, ephedrine and pseudoephedrine be deleted from the current formulary.

Response 10: The Board notes that the proposed rule notice did not include the suggested deletion of the three substances. The Board is unable to delete them at this time, as the public would not be provided notice of the deletion or any opportunity to comment on the amendments.

4. The Board amends ARM 24.111.301, ARM 24.111.602 and ARM 24.111.613 exactly as proposed.

5. After consideration of the comments, the Board has amended ARM 24.111.511 exactly as proposed, but with the following changes, stricken matter interlined, new matter underlined:

24.111.511 NATUROPATHIC PHYSICIAN NATURAL SUBSTANCE FORMULARY LIST (1) through (3)(a)(iv) remain as proposed.

- (v) ketoconazole for topical use;
- (vi) through (g)(i) remain as proposed.
- (ii) trimethoprim/sulfamethoxazole, ~~and~~ .
- ~~(h) floroquinolone derivatives:~~
- ~~(i) ciprofloxacin,~~
- ~~(ii) levofloxacin, and~~
- ~~(iii) ofloxacin,~~
- (4) through (10)(a)(v) remain as proposed.
- (vi) ~~prgenenolone~~ pregnenolone; and
- (vii) through (17) remain as proposed.

AUTH: 37-1-131, 37-26-201, MCA

IMP: 37-26-301, MCA

BOARD OF ALTERNATIVE HEALTH CARE
DOLLY BROWDER, LM, CHAIRPERSON

9-5/12/05

Montana Administrative Register

/s/ KEITH KELLY

Keith Kelly, Commissioner
DEPARTMENT OF LABOR AND INDUSTRY

/s/ DARCEE L. MOE

Darcee L. Moe
Alternate Rule Reviewer

Certified to the Secretary of State May 2, 2005